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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,861	LEE ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *7-13,15-21,28,29 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,14,22-27,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/04, 12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 6/24/2004, in which claims 4, 5, 10, 11, 19 and 21 were amended. Receipt is also acknowledged of an amendment, filed 12/22/2005, in which claims 15-18 were amended, and claims 22-32 were newly added. Currently, claims 1-32 are pending.

Election/Restrictions

Applicant's election without traverse of Group I (claims 2-6, and linking claims 1 and 14) in the reply filed on 12/22/2005 is acknowledged.

New claims 22-27 and 30-31 read on the elected invention.

New claims 28 and 29 read on the non-elected invention of Group III, as set forth in the Office action mailed 9/22/2005.

New claim 32 reads on the invention of Group V, as set forth in the Office action mailed 9/22/2005.

Claims 7-13, 15-21, 28, 29 and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/22/2005.

An examination on the merits of claims 1-6, 14, 22-27 and 30-31 follows.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/338,441, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior-filed provisional application does not provide teach how to make and use an isolated transcription factor that comprises at least one zinc finger domain, wherein the presence of the transcription factor in a cell can alter the differentiation state of the cell. The provisional application does not describe proteins that comprise at least one zinc finger domain and can alter the differentiation state of a cell. The specification of the provisional application does not describe zinc fingers that can induce a neuronal phenotype in a vertebrate cells such as a neuroblastoma cell. The specification of the provisional application does not describe a protein comprising a first, second and third zinc finger domains, wherein the contacting residues of the first, second, and third domains at

positions –1, 2, 3, and 6 of each domain respectively correspond to the motifs: QSNR, ZSNK, and CSNR, such as the zinc finger array of SEQ ID NO: 2.

Claims 1-6, 14, 22-27 and 30-31 have an effective filing date of 4/26/2002.

Information Disclosure Statement

Receipt of information disclosure statements, filed on 9/24/2006 and 6/24/2004, is acknowledged. The signed and initialed PTO 1449s have been mailed with this action.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

Applicant should review the entire application and fully comply with all sequence rules. For example, the application fails to comply with the sequence rules because the specification contains the amino acid consensus sequence for a homeodomain on page 54, paragraph 3. This sequence is not referred to by the use of a sequence identifier.

In response to this office action, Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. The nature of the non-compliance did not preclude an examination of the elected invention on the merits, the results of which are presented below.

Drawings

The drawings were received on 9/24/2003. Replacement drawings were received on 6/24/2004. The drawings are accepted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-19 of copending Application No. 10/538,041, as evidenced by Cross et al (TRENDS in Pharmacological Scie4nces, Vol. 22, No. 4, pages 201-207, April 2001).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been

obvious over, the reference claim(s). See, e.g. *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 is generic to all that is recited in claims 1-11 and claims 16-19 (as they read on the polypeptide of conflicting claim 1) of the 10/538,041 application. That is, claims 1-11 and 16-19 (as they read on the polypeptide of conflicting claim 1) of the 10/538,041 application falls entirely with the scope of claim 1 of the instant application or, in other words, instant claim 1 is anticipated by claims 1-11 and 16-19 of the 10/538,041 application. Instant claim 14 is generic to all that is recited in claims 14 and 15 of the 10/538,041 application. That is, claims 14 and 15 of the 10/538,041 application falls entirely with the scope of claim 14 of the instant application or, in other words, instant claim 14 is anticipated by claims 14 and 15 of the 10/538,041 application. Specifically, the polypeptides claimed in the 10/538,041 application contain at least one zinc finger domain, wherein the presence of the transcription factor in the cell can alter the differentiation state of the cell. The conflicting claims are drawn to polypeptides that can bind to a site in the VEGF gene. Altered VEGF expression results in altered differentiation with regard to biological processes such as angiogenesis (Cross et al., e.g. page 201).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14, 30 and 31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The specification envisions embodiments where the cell is present or intended to be present in a human being, which is non-statutory subject matter. As such, the recitation of the limitation "non-human" would be remedial. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 6, 22, 23, 26, 27 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite in that the metes and bounds of the phrase "positions –1, 2, 3 and 6 of the domain correspond to a motif selected from the group consisting of: QSNR, QSNK, and CSNR" are unclear. The nature of the correspondence is unclear. The correspondence can be interpreted as being a direct correspondence where positions –1, 2, 3 and 6 of the domain are selected from the group of motifs consisting of QSNR, QSNK, and CSNR.

Alternatively, the correspondence could be indirect, where the motif has substitutions within the motifs selected from the group consisting of QSNR, QSNK, and CSNR.

Claim 5 is vague and indefinite in that the metes and bounds of the phrase "the DNA contacting residues of the first, second, and third domains at positions –1, 2, 3, and 6 of each domain respectively correspond to the motifs: QSNR, QSNK, and CSNR" are unclear. The nature of the correspondence is unclear. The correspondence can be interpreted as a direct correspondence, where the motifs are QSNR, QSNK, and CSNR, respectively. Alternatively, the correspondence could be indirect, where the motif has substitutions within the motifs QSNR, QSNK, and CSNR.

Claims 6, 26, 27 and 31 depend from claim 5 and are indefinite for the same reasons as applied to claim 5.

Claim 6 is vague and indefinite in that the metes and bounds of the phrase "zinc finger array in SEQ ID NO: 2" are unclear. The phrase is unclear in that the term "zinc finger array" is not defined in the present specification, and there is no clear art-recognized definition. Thus, one would not be apprised of the scope of the invention. For example, the zinc finger array may consist of the zinc finger consensus sequence, including the cysteine, histidines and spacing thereof. Alternatively, the array may consist of the amino acid sequence of the zinc fingers of SEQ ID NO: 2. If so, it is not clear exactly which amino acids comprise the zinc finger array of SEQ ID NO: 2. Does the array start with the first cysteine of the first zinc finger? Does it start with an amino acid located closer to the n-terminus of the protein? It would be remedial to amend the claim language to clearly indicate the sequence encompassed by the phrase "zinc finger array in SEQ ID NO: 2."

Claim 27 depends from claim 6 and is indefinite for the same reasons as applied to claim 6.

Claim 22 recites the limitation "zinc finger domains" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 22 depends from claim 2, which depends from claim 1. Claim 1 recites an isolated transcription factor that comprises "at least one zinc finger domain." Claim 1 encompasses proteins with more than one zinc finger but does not require the transcription factor to have more than one zinc finger.

Claim 23 depends from claim 22 and is indefinite for the same reasons as applied to claim 22.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 5, 6, 14, 22-27, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to or encompass a transcription factor that comprises at least one zinc finger and is capable of altering the differentiation state of a cell. The independent claims limit the structure of the zinc finger polypeptide to one that is capable of inducing a neuronal phenotype in the cell, including neurite extension. Claims 1-3, 14, 24, 25 and 30 are drawn to or

encompass a transcription factor defined by the presence of a single zinc finger structure of any sequence and any function (DNA binding or protein-protein interaction) and by function. Claim 4 is drawn to a transcription factor comprising at least one zinc finger domain, wherein the DNA contacting residues of the zinc finger domain at positions –1, 2, 3 and 6 of the domain correspond to a motif selected from the group consisting of : QSNR, QSNK, and CSNR. Further, claim 4 reads on transcription factor proteins containing modified motifs of QSNR, QSNK, and CSNR. Claims 5, 6, 26, 27 and 31 are drawn to or encompass a transcription factor comprising a first, second and third zinc finger domain, wherein the DNA contacting residues of the first, second and third domains at positions –1, 2, 3 and 6 of each domain respectively "correspond to" the motifs QSNR, QSNK, and CSNR. Thus, claims 5, 6, 26, 27 and 31 encompass proteins with modifications to the motifs of QSNR, QSNK, and CSNR. Claims 22 and 23 are drawn to a set of isolated transcription factors that comprise at least one zinc finger domain, wherein the zinc finger domain(s) are selected from different naturally occurring proteins. Claim 23 further limits the naturally occurring proteins to human proteins. The isolated transcription factors must be capable of inducing a neural phenotype in a cell.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification envisions designing transcription factors to alter the differentiate state of a cell to a neural phenotype as evidenced by neurite extension, synapse formation, or neural marker expression (e.g. paragraph bridging pages 11-12; paragraph bridging

pages 19-20). The specification envisions the production of proteins comprising a zinc finger domain corresponding to a motif selected from the group consisting of QSNR, QSNK, and CSNR, wherein the amino acids represent contacting residues of the zinc finger domain at positions –1, 2, 3 and 6, respectively (e.g. page 18, last paragraph). The specification asserts that polypeptides comprising the following sequences are capable of inducing neurites when present at an effective concentration in a Neuro2a cell (e.g. page 28):

$CX_{(2-5)}CXXXBXQXSNJXRHX_{(3-5)}HX_{(1-6)}BXCX_{(2-5)}CXXXBXQXSNJXKH$
$X_{(3-5)}HX_{(1-6)}BXCX_{(2-5)}CXXXBXCXSNJXRHX_{(3-5)}H$ (SEQ ID NO:36),

where B is any amino acid, or optionally phenylalanine or tyrosine; and J is any amino acid, or optionally, a hydrophobic amino acid. This array is also abbreviated as: QSNR-QSNK-CSNR. Other exemplary artificial polypeptides include:

$CX_{(2-5)}CXXXBXQXSNJXRHX_{(3-5)}HX_{(1-6)}BXCX_{(2-5)}CXXXBXQXSNJXKHX_{(3-5)}H$ (SEQ ID NO:37), and

$CX_{(2-5)}CXXXBXQXSNJXKHX_{(3-5)}HX_{(1-6)}BXCX_{(2-5)}CXXXBXCXSNJXRHX_{(3-5)}H$ (SEQ ID NO:38).

The specification describes the amino acid sequence of Neuro1-p65 chimeric zinc finger protein (SEQ ID NO: 2). The specification teaches that the polypeptide of SEQ ID NO: 2 is capable of inducing neurite formation in Neuro2a cells (e.g. Figure 8). The Neuro1-p65 protein of SEQ ID NO: 2 is composed of includes the zinc finger domains QSNR-QSNK-CSNR and the p65 activation domain (e.g. paragraph bridging pages 48-49). The specification asserts that other artificial proteins with at least two or three consecutive zinc finger domains that have the same pattern of DNA contacting residues as domains in QSNR-QSNK-CSNR-p65 may also induce neurites (paragraph bridging pages 48-49). No evidence is provided to demonstrate that these sequence variants are capable of inducing neurite formation. No structure-function correlation is

provided in the present specification for any zinc finger protein other than Neuro1-p65 comprising the QSNR-QSNK-CSNR motif linked to an activation domain. Although the specification describes numerous naturally occurring zinc fingers from proteins isolated from human, the specification does not provide a correlation between the zinc finger(s) and neural differentiation.

To isolate the polypeptide of SEQ ID NO: 2, Applicant screened three-finger and four-finger zinc finger protein transcription factor (ZFP-TF) libraries, constructed using 40 and 25 zinc finger domains respectively (e.g. Example 1; page 108, last paragraph). The zinc finger proteins were expressed as fusions with a p65 transcriptional activation domain and to the KRAB repression domain (e.g. page 108, last paragraph). To screen for ZPF-TF capable of inducing neuronal differentiation, Neuro2A cells were transiently transfected with library plasmids and assayed for neuritogenesis (e.g. page 109). The specification asserts that several ZFP-TFs were identified, with Neuro1-p65 having the most prominent effect on differentiation (e.g. page 109). Further, the specification teaches that mutations that disable the binding activity of the zinc finger domains of Neuro1-p65 abolish its ability to support neurogenesis (e.g. page 110). The specification does not describe the sequence of the ZFP-TFs capable of inducing neural differentiation, except for Neuro1-p65 (SEQ ID NO: 2).

The specification describes a single protein capable of inducing neuronal differentiation: SEQ ID NO: 2. Further, the specification describes the structure required for this protein to function: three zinc finger domains and a transcriptional activation domain, wherein the first, second and third zinc finger domains have contacting residues at positions –1, 2, 3 and 6 that are

QSNR, QSNK, and CSNR, respectively. The specification does not adequately describe any other protein capable of inducing neural differentiation.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of a subgenus of the claimed proteins. The results are not necessarily predictive of the full scope of the claimed genus. Thus, it is impossible for one to extrapolate from the examples described herein those transcription factors that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification. The prior art and post-filing art disclose proteins comprising a zinc finger, wherein the DNA contacting residues of the zinc finger domain at positions –1, 2, 3 and 6 of the domain are QSNR. The proteins disclosed as GenBank Accession Nos. BAA31413 (2/13/1999), AAS67595 (11/30/2004), and P17022 (2/7/2006) each comprise a zinc finger domain with contacting residues QSNR. However, there is no evidence that these proteins are capable of inducing neural differentiation. The description of BAA31413 indicates that the protein is a putative transcriptional repressor regulating G2/M transition. The description of AAS67595 and P17022 suggest that the proteins function in heart development. The expression pattern of Zinc finger protein 18 (P17022) provides evidence that the gene is expressed in extraembryonic tissues of E7.5 mouse embryo, anterior trunk, tail and heart of the E9.0 embryo, and in the heart at E10.5, suggesting that ZNF18 may play a role in the development of the embryonic heart (Yi Chuan, Vol. 27, No. 4, pages 523-530, 2005; Abstract only). The non-patent literature suggests that zinc finger proteins comprising a zinc finger domain with contacting residues QSNR may function in

developmental pathways other than neural development. Thus, not all proteins comprising the zinc finger sequence will necessarily be capable of inducing a neural phenotype in a cell.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed protein structure of the encompassed genus of transcription factors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Given the very large genus of isolated transcription factors encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to the structure required to induce a neural phenotype, the skilled artisan would not have been able to envision a sufficient number of specific embodiments that meet the functional limitations

of the claims to describe the broadly claimed genus of transcription factors. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those transcription factors that satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1-4, 5, 6, 14, 22-27, 30 and 31.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14, 24, 25 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellefroid et al (Cell, Vol. 87, pages 1191-1202, 1996; see the entire reference).

Bellefroid et al teach the transcription factor protein X-MyT1, which is a C2HC-type zinc finger protein capable of inducing a neuronal phenotype and neurite extension in a cell such as a mouse neuroblastoma cell (e.g. Figure 1page 1192, left column, 1st full paragraph). Bellefroid et al teach that S-MyT1 contains a transcriptional activation domain (e.g. pages 1197-1198, X-MyT1 Acts as a Transcriptional Activator; Decreasing Its Activity Affects the Pattern of Neuronal Differentiation). Further, Bellefroid et al teach a cell that contains the X-MyT1 transcription factor (e.g. page 1201, Microinjection Procedures, and DNA Transfection and CAT Assays).

Claims 1-3, 14, 24, 25 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamar et al (Development, Vol. 128, pages 1335-1346, April 15, 2001; see the entire reference).

Lamar et al teach the transcription factor protein NKL, a C2H2-type zinc finger protein capable of inducing a neural phenotype and neurite extension in a cell such as a mouse neuroblastoma cell (e.g. page 1336, left column, second full paragraph; Figure 1). Further, Lamar et al teach a fusion protein comprising the zinc fingers of NKL and a heterologous VP16 activation domain (e.g. page 1336, Constructs). Moreover, Lamar et al teach chick cells comprising the NKL/VP16 fusion protein (e.g. paragraph bridging pages 1336-1337).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al (Development, Vol. 124, pages 3123-3134, 1997; see the entire reference).

Klein et al teach the transcription factor protein *klumpfuss* (*klu*), a C2H2-type zinc finger protein capable of altering the differentiation of bristle differentiation in *Drosophila* (e.g. paragraph bridging pages 3123-3124; page 3133; Figure 1).

Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dreyer et al (Human Molecular Genetics, Vol. 9, No. 7, pages 1067-1074, 2000; see the entire reference) as evidenced by Curtiss et al (Bioessays, Vol. 20, No. 1, pages 58-69; see the entire reference).

Dreyer et al teach the transcription factor protein LMX1B, a LIM-homeodomain transcription factor capable of altering the differentiation of limb and renal differentiation (e.g. page 1067, right column; Figure 1; page 1073, Plasmid constructs, and Cell culture). Further,

Dreyer et al teach a cell comprising the LMX1B transcription factor (e.g. page 1073, Cell culture).

Curtiss et al is cited only to show that each LIM domain is composed of two C2H2 zinc fingers (e.g. page 58, paragraph bridging columns; Figure 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston

Examiner
Art Unit 1636

jad

CELINE QIAN, PH.D.
PRIMARY EXAMINER